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## FACSIMILE COVER SHEET

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June 5, 2003

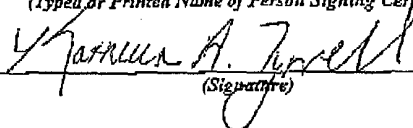
**TO: Examiner Yu (TC1600)****GROUP: 1642****FAX NUMBER: 703-872-9306****ATTORNEY DOCKET NO.: DEX-0176****SERIAL NO.: 09/787,844****FILED: August 6, 2001****NUMBER OF PAGES: 7****MESSAGE:****Kathleen A. Tyrrell, Registration No. 38,350****URGENT! PLEASE DELIVER IMMEDIATELY UPON RECEIPT. THANK YOU!**

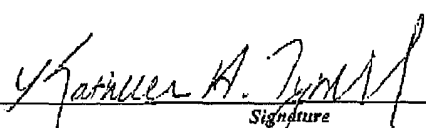
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|  |                               |                        |                        |
|--|-------------------------------|------------------------|------------------------|
| <b>CERTIFICATE OF TRANSMISSION BY FACSIMILE (37 CFR 1.8)</b>   |                               |                        | Docket No.             |
| Applicant(s): Ali et al.   |                               |                        | DEX-0176               |
| Serial No.<br>09/787,844   | Filing Date<br>August 6, 2001 | Examiner<br>Yu, Misook | Group Art Unit<br>1642 |
| Invention: Method of Diagnosing, Monitoring, Staging, Imaging and Treating Gynecologic Cancers and Testicular Cancer   |                               |                        |                        |
| <p>I hereby certify that this <u>Reply to Restriction Requirement</u><br/>(Identify type of correspondence)<br/>is being facsimile transmitted to the United States Patent and Trademark Office (Fax. No. <u>703-872-9306</u>)<br/>on <u>June 5, 2003</u><br/>(Date)</p> <p style="text-align: right;"><u>Kathleen A. Tyrrell</u><br/>(Typed or Printed Name of Person Signing Certificate)<br/><br/>(Signature)</p> <p style="text-align: center;">Note: Each paper must have its own certificate of mailing.</p> |                               |                        |                        |

|   |                                      |                               |                                |                               |                   |
|---|--------------------------------------|-------------------------------|--------------------------------|-------------------------------|-------------------|
| <b>AMENDMENT TRANSMITTAL LETTER (Large Entity)</b>  |                                      |                               |                                | Docket No.<br><b>DEX-0176</b> |                   |
| Applicant(s): <b>Ali and Cafferkey</b>  |                                      |                               |                                |                               |                   |
| Serial No.<br><b>09/787,844</b>   | Filing Date<br><b>August 6, 2001</b> | Examiner<br><b>Yu, Misook</b> | Group Art Unit<br><b>1642</b>  |                               |                   |
| Invention: <b>Method of Diagnosing, Monitoring, Staging, Imaging and Treating Gynecologic Cancers and Testicular Cancer</b>   |                                      |                               |                                |                               |                   |
| <u>TO THE COMMISSIONER FOR PATENTS:</u>   |                                      |                               |                                |                               |                   |
| Transmitted herewith is an amendment in the above-identified application.<br>The fee has been calculated and is transmitted as shown below.   |                                      |                               |                                |                               |                   |
| <b>CLAIMS AS AMENDED</b>  |                                      |                               |                                |                               |                   |
|   | CLAIMS REMAINING<br>AFTER AMENDMENT  | HIGHEST #<br>PREV. PAID FOR   | NUMBER EXTRA<br>CLAIMS PRESENT | RATE                          | ADDITIONAL<br>FEE |
| TOTAL CLAIMS  | 15 -                                 | 20 =                          | 0 x                            | \$18.00                       | \$0.00            |
| INDEP. CLAIMS   | 6 -                                  | 6 =                           | 0 x                            | \$84.00                       | \$0.00            |
| Multiple Dependent Claims (check if applicable) <input type="checkbox"/>  |                                      |                               |                                |                               | \$0.00            |
| <b>TOTAL ADDITIONAL FEE FOR THIS AMENDMENT</b>  |                                      |                               |                                |                               | <b>\$0.00</b>     |
| <div style="display: flex; justify-content: space-between;"><div><input checked="" type="checkbox"/> No additional fee is required for amendment.<br/><input type="checkbox"/> Please charge Deposit Account No. _____ in the amount of _____<br/><input type="checkbox"/> A check in the amount of _____ to cover the filing fee is enclosed.<br/><input checked="" type="checkbox"/> The Director is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. <b>50-1619</b><br/><input checked="" type="checkbox"/> Any additional filing fees required under 37 C.F.R. 1.16.<br/><input checked="" type="checkbox"/> Any patent application processing fees under 37 CFR 1.17.</div><div style="text-align: right;">Dated: <b>June 5, 2003</b></div></div> <div style="margin-top: 20px;"><div style="display: flex; justify-content: space-between;"><div style="width: 60%;"><br/>_____<br/>Signature<br/><b>Kathleen A. Tyrrell, Reg. No. 38,350</b></div><div style="width: 35%; border: 1px solid black; padding: 5px;"><p>I certify that this document and fee is being deposited on _____ with the U.S. Postal Service as first class mail under 37 C.F.R. 1.8 and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.</p><p style="text-align: center;">_____<br/>Signature of Person Mailing Correspondence</p><p style="text-align: center;">_____<br/>Typed or Printed Name of Person Mailing Correspondence</p></div></div><div style="margin-top: 20px;">cc: _____</div></div> |                                      |                               |                                |                               |                   |

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: DEX-0176  
Inventors: Ali et al.  
Serial No.: 09/787,844  
Filing Date: August 6, 2001  
Examiner: Yu, Misook  
Group Art Unit: 1642  
Title:

## Certificate of Facsimile Transmission

I hereby certify that this document is being facsimile transmitted to the Patent and Trademark Office on the date shown below.

On June 5, 2003

  
Kathleen A. Tyrrell, Registration No. 36,350

Mail Stop  
Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Reply to Restriction Requirement

This is a reply to the Restriction Requirement mailed May 5, 2003 setting a one (1) month statutory period for response. Please enter the following remarks into the record.

## REMARKS

Claims 1-11 are pending in the instant application. Claims 1-11 have been subjected to restriction as follows:

Group I, claims 1-6, drawn to a method of cancer diagnosis

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by detecting CSG level in a sample of patient;

Group II, claim 7, drawn to an antibody to SEQ ID NO:1; and  
Group III, claims 8-11, drawn to *in vivo* imaging using an  
antibody.

The Examiner suggests that the invention listed as Groups I-III do not relate to a single general inventive concept under Rule PCT 13.1 because, under Rule 13.2, they lack the same or corresponding special technical feature. The Examiner suggests that the special technical feature of Group I is using CSG levels in a patient's sample to diagnose cancer, the special technical feature of Group II is the antibody to SEQ ID NO:1 and the special technical feature of Group III is use of the antibody in *in vivo* imaging.

Applicants respectfully traverse this Restriction Requirement.

At the outset, Applicants respectfully disagree with the Examiner's characterization of the special technical feature of claims 1-11. The special technical feature linking claims 1-11 is the recognition that the CSG of SEQ ID NO:1 is a specific marker for gynecologic and testicular cancers. Thus, contrary to the Examiner's suggestion, the claims, which are drawn to a method of diagnosis of gynecologic and testicular cancers based

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upon detection of the CSG, and an antibody and method of using the antibody against the CSG, for imaging and treating gynecologic and testicular cancers clearly share the same special technical feature.

Further, the Examiner's suggestion that "the inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature" directly contradicts the Examination Report issued by the PCT of which this case is the U.S. National Stage.

MPEP §803 provides two criteria which must be met for a restriction requirement to be proper. The first is that the inventions be independent or distinct. The second is that there would be a serious burden on the Examiner if the restriction is not required. A search of the prior art relating to pending claims 1-11 has already been performed in the PCT application. Thus, there is clearly no burden placed upon the Examiner by including all claims in this case, since the full claim set was already searched and examined in the PCT application.

Further, the Examiner has provided no evidence in this Restriction Requirements to support the contention that the Groups have acquired separate status in the art.

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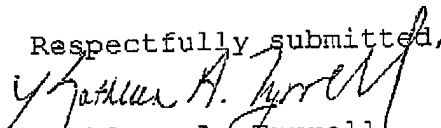
Accordingly, since this Restriction Requirement does not meet both criteria as set forth in MPEP § 803 to be proper, it is respectfully requested that this Restriction Requirement be withdrawn.

Accordingly, reconsideration and withdrawal of this Restriction Requirement is respectfully requested.

However, in an earnest effort to be completely responsive, Applicants elect to prosecute Group III, claims 8-11, with traverse.

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record.

Respectfully submitted,

  
Kathleen A. Tyrrell  
Reg. No. 38,350

Date: June 5, 2003

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